K010335

SEP 2 7 2001

Bio-Medical Research Ltd
Parkmore Business Park, West
Galway
Ireland

510 (k) Summary of Safety and Effectiveness.

This summary is submitted in accordance with 21 CFR 807.92

a)	1	Submitted by	Bio-Medical Research Ltd BMR House Parkmore Business Park, West Galway Republic of Ireland
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		Title	Technical Director
		Date of Preparation	15 January 2001 revised 18 September 2001
	2	Trade Name of Device	Slendertone Flex
		Common Name	Muscle Stimulator
		Classification name	Powered Muscle Stimulator
	3	Identification of predicate device	EMS+2 Staodyn Inc K926510
	4	Description of Device	

Slendertone Flex is a two channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It comprises two main components,

namely, an electronic stimulator module which generates the required stimulation signals, and an abdominal electrode belt which connects the signals from the stimulator to the skin electrodes located on the inner surface of the belt. In effect, the belt in this case takes the place of the leadwires in most conventional muscle stimulators.

The product is supplied with a set of double sided adhesive electrodes, an instruction manual, a set of batteries, and a carry pouch. Power is derived from three RO3 cells located in a compartment protected by a removable battery cover.

Although a two channel system, there are only three electrodes, since the central umbilical electrode is common to the each of the left and right stimulation circuits. The electrodes connect adhesively to studs on the inner surface of the belt. The user extends the belt and puts it on in a wrapping motion from front to back, closing it at the back using the Velcro patches. When the belt is in place on the body the larger center electrode locates over the umbilicus and the two side electrodes locate on either side of the body towards the mid axillary line, between the pelvis and the ribcage. It has been found that this electrode positioning is particularly useful for stimulating the abdominal muscles.

The pulsed stimulation current passes between the side and center electrodes only. There is no current passed from side to side. Because the user has no access to the wiring or connectors within the belt, he/she cannot alter the current path and so the possibilities for mis-use are greatly reduced

5 Intended Use

The Slendertone Flex device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the purpose improving abdominal muscle tone.

The device is indicated for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for developing a firmer abdomen.

6 Technological Comparison

The Slendertone Flex device is similar to the EMS+2 in that it delivers a stimulation signal which is almost identical to the EMS+2 with similar parameter settings. The Slendertone Flex device is much more restricted in its range of available stimulation parameters than the EMS+2. The Slendertone Flex device is also more restricted in terms of electrode positioning compared to the EMS+2, since the electrodes are integrated in the belt. The Slendertone Flex device has an LCD screen with user compliance logging, whereas the EMS+2 does not have these features.

b) 1 Non Clinical Tests

Comparisons of electrical outputs for the Slendertone Flex device and the predicate EMS+2 show similar results. The Slendertone Flex device was designed to, and has been independently tested to IEC 601-1: 1988 + A1: 1991 + A2: 1995, IEC 601-2-10: 1987, IEC 601-1-2: 1993. Bio-Medical Research Ltd, (BMR), adheres to recognised and established industry practice, and all devices are subject to final performance testing. A hazard analysis, a risk analysis and a failure mode effects analysis have been carried out for the Slendertone Flex device.

2 Clinical Tests.

BMR conducted a prospective, controlled, single blind clinical study with 72 female volunteers to measure the effects of a program of abdominal EMS over an eight week period, using the electrode positions and stimulation parameters of the Slendertone Flex product. The study was designed and carried out by BMR at its consumer research center in Galway, Ireland.

In psychometric tests, the treated group in the study reported a marked improvement in firmness and hardness compared to the control group over the period of the study. Moreover, the treated group showed improvements in self-image and well being. The control group did not report such an improvement.

In objective measurements of abdominal muscle strength, the treated group showed an average increase in muscle strength of 12%, while the control group showed a marginal dis-improvement between the "before" and "after" measurements.

There was no significant change measured in abdominal girth or body weight for either group.

3 Test Conclusions

Testing of the stimulation output parameters of the Slendertone Flex device indicates that it is safe, and that it provides appropriate stimulation output for the abdominal muscle group. The clinical testing indicates that users experience a clinically significant improvement in muscle tone, abdominal muscle strength and abdominal muscle firmness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Bio-Medical Research, Ltd.
c/o Mr. Robert Dormer
Hyman, Phelps & McNamara, P.C.
700 13th Street NW
Suite 1200
Washington, D.C. 20005

Re: K010335
Trade/Device Name: Slendertone™ FLEX, Model 512
Regulation Number: 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: July 2, 2001
Received: July 2, 2001

Dear Mr. Dormer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K010335

Device Name: Slendertone Flex, type 512
Sponsor Name: Bio-Medical Research Ltd.

Indications for Use:

Slendertone Flex is indicated for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for the development of a firmer abdomen.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☐
Over-The-Counter Use ☐

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010335